

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>( Not for submission under 37 CFR 1.99)</i>	Application Number		09423698	
	Filing Date		2000-02-10	
	First Named Inventor		Odile Leroy	
	Art Unit		1645	
	Examiner Name		P.A. Duffy	
	Attorney Docket Number		99-849-A	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS						Remove		
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1							<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS						Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>5</sup>
						<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>( Not for submission under 37 CFR 1.99)</i>	Application Number		09423698
	Filing Date		2000-02-10
	First Named Inventor		Odile Leroy
	Art Unit		1645
	Examiner Name		P.A. Duffy
	Attorney Docket Number		99-849-A

	1	Klein, "Pneumococcal Conjugate Vaccines: Review and Update", Microbial Drug Resistance, 1995, 49-58, 1(1), Mary Ann Liebert, Inc.	<input type="checkbox"/>
	2	Fattom et al., "Overload of Homologous Carrier Protein at the Site of Injection Might Cause A Reduced Immunogenicity of Capsular Polysaccharide Conjugate Vaccines", Abstracts of the 36th ICAAC, 160, Nabi-Rockville, USA.	<input type="checkbox"/>
	3	Ahman et al., "Immunogenicity of Octavalent Pneumococcal (Pnc) Conjugate Vaccines (PncD, PncT) In Finnish Infants", Abstracts of the 36th ICAAC, 1 page, Tuesday, Session 61, Nabi-Rockville, USA.	<input type="checkbox"/>
	4	Dagan et al., "Reduction of Antibody Response To An 11-Valent Pneumococcal Vaccine Coadministered With A Vaccine Containing Acellular Pertussis Components", Infection And Immunity, Sept. 2004,, 5383-5391, 72(9), American Society for Microbiology.	<input type="checkbox"/>
	5	Ortqvist et al., "Pneumococcal Capsular Polysaccharide Vaccine (PCPV) For Prevention Of Pneumonia In Middle-Aged And Elderly Persons: A Prospective, Randomized, Placebo-Controlled Multicenter-Trial", Abstracts of the 36th ICAAC, 1 page, Tuesday Session 61, Nabi-Rockville, USA.	<input type="checkbox"/>
	6	Holmes et al., "Immunogenicity of Four Haemophilus Influenzae Tybe b Conjugate Vaccines In 17- to 19-month-old Children", The Journal of Pediatrics, March 1991, 364-371, 118(3), St. Louis, USA.	<input type="checkbox"/>
	7	"Pertussis Vaccines/Pneumococcal Vaccines", Martindale: The Extra Pharmacopoeia, 1996, 11 pages, Royal Pharmaceutical Society.	<input type="checkbox"/>
	8	Olander et al., "Booster Response to the Tetanus and Diphtheria Toxoid Carriers of 11-Valent Pneumococcal Conjugate Vaccine In Adults and Toddlers", Vaccine 20, 2002, 336-341, Elsevier.	<input type="checkbox"/>
	9	Puumalainen et al., "Greater Antibody Responses to an Eleven Valent Mixed Carrier Diphtheria- or Tetanus-Conjugated Pneumococcal Vaccine in Filipino Than in Finnish or Israeli Infants", The Pediatric Infectious Disease Journal, Feb. 2003, 141-149, 22(2).	<input type="checkbox"/>
	10	Sigurdardottir et al., "Immune Response to Octavalent Diphtheria- and Tetanus-Conjugated Pneumococcal Vaccines Is Serotype- and Carrier-Specific: The Choice for a Mixed Carrier Vaccine", The Pediatric Infectious Disease Journal, 2002, 548-554, 21(6).	<input type="checkbox"/>
	11	"Board Accepts 'Reward' Approach To Funding Must Be Postponed", GAVI Immunization Focus, March 2002, 1-8.	<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>( Not for submission under 37 CFR 1.99)</i>	Application Number		09423698
	Filing Date		2000-02-10
	First Named Inventor		Odile Leroy
	Art Unit		1645
	Examiner Name		P.A. Duffy
	Attorney Docket Number		99-849-A

	12	Eick et al., "Safety and Immunogenicity of Two Octavalent Pneumococcal Conjugate Vaccines in American Indian Infants", Vaccine 22, 2004, 1260-1264, Elsevier.	<input type="checkbox"/>
	13	Nurkka et al., "Serum and Salivary Anti-Capsular Antibodies in Infants and Children Vaccinated With Octavalent Pneumococcal Conjugate Vaccines, PncD and PncT", Vaccine 20, 2002, 194-201, Elsevier.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

#### EXAMINER SIGNATURE

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <b>( Not for submission under 37 CFR 1.99)</b>	Application Number		09423698
	Filing Date		2000-02-10
	First Named Inventor		Odile Leroy
	Art Unit		1645
	Examiner Name		P.A. Duffy
	Attorney Docket Number		99-849-A

### CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- See attached certification statement.  
 Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.  
 None

### SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Michael S. Greenfield/	Date (YYYY-MM-DD)	2006-06-15
Name/Print	Michael S. Greenfield	Registration Number	37142

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.